

and Package Code and FDA will assign a Labeler Code as described in § 207.35(b)(2)(i).

(c) For each drug product listed that is subject to the imprinting requirements of part 206 of this chapter, including products that are exempted under § 206.7(b), drug companies must submit a document that provides the name of the product, its active ingredient(s), dosage strength, National Drug Code number, the name of its manufacturer or distributor, its size, shape, color, and code imprint (if any), and any other characteristic that identifies the product as unique.

[45 FR 38043, June 6, 1980, as amended at 52 FR 2682, Jan. 26, 1987; 55 FR 11577, Mar. 29, 1990; 58 FR 47959, Sept. 13, 1993; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999]

§ 207.26 Amendments to registration.

Changes in individual ownership, corporate or partnership structure location or drug-handling activity, shall be submitted by Form FDA-2656 (Registration of Drug Establishment) as amendment to registration within 5 days of such changes. A change in a registered establishment's firm name within 6 months of the registration of the establishment is required to be supported by a signed statement of the establishment's owner or operator that the change is not made for the purpose of changing the name of the manufacturer of a drug product under § 201.1 of this chapter. Changes in the names of officers and directors of the corporations do not require such amendment but must be shown at time of annual registration.

[45 FR 25777, Apr. 15, 1980, as amended at 55 FR 11577, Mar. 29, 1990]

§ 207.30 Updating drug listing information.

(a) After submitting the initial drug listing information, every person who is required to list drugs under § 207.20 shall submit on Form FDA-2657 (Drug Product Listing) during each subsequent June and December, or at the discretion of the registrant when the change occurs, the following information:

(1) A list of each drug introduced by the registrant for commercial distribution which has not been included in

any list previously submitted. The registrant shall provide all of the information required by § 207.25(b) for each such drug.

(2) A list of each drug formerly listed in accordance with § 207.25(b) for which commercial distribution has been discontinued, including for each drug so listed the National Drug Code (NDC) number, the identity by established name and by proprietary name, and date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(3) A list of each drug for which a notice of discontinuance was submitted under paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each drug so listed the NDC number, the identity by established name and by proprietary name, the date of resumption, and any other information required by § 207.25(b) not previously submitted.

(4) Any material change in any information previously submitted.

(b) When no changes have occurred since the previously submitted list, no report is required.

§ 207.31 Additional drug listing information.

(a) In addition to the information routinely required by §§ 207.25 and 207.30, FDA may require submission of the following information by letter or by FEDERAL REGISTER notice:

(1) For a particular prescription drug so listed that the registrant regards as not subject to section 505 of the act, upon request by FDA for good cause, a copy of all advertisements.

(2) For a particular drug product so listed that the registrant regards as not subject to section 505 or 512 of the act, upon a finding by FDA that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For a particular drug product, upon request by FDA, a brief statement of the basis for the registrant's belief that the drug product is not subject to section 505 or 512 of the act.

(4) For each registrant, upon a finding by FDA that it is necessary to carry out the purposes of the act, a list

of each listed drug product containing a particular ingredient.

(b) It is requested but not required that a qualitative listing of the inactive ingredients be submitted for all listed drugs in the format prescribed in Form FDA-2657 (Drug Product Listing).

(c) It is requested but not required that a quantitative listing of the active ingredients be submitted for all drugs listed that are subject to section 505 or 512 of the act or section 351 of the Public Health Service Act.

[45 FR 38043, June 6, 1980, as amended at 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999]

§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

(a) FDA will provide to the registrant a validated copy of Form FDA-2656 (Registration of Drug Establishment) as evidence of registration. This validated copy will be sent to the mailing address shown on the form. FDA will assign a permanent registration number to each drug establishment registered in accordance with these regulations.

(b) Using the National Drug Code (NDC) numbering system, FDA assigns a drug listing number to each drug or class of drugs listed as follows:

(1) If a drug is already listed in the National Drug Code System or in the National Health Related Items Code System, the number is the same as that assigned under those codes. FDA adds a lead zero to the first three characters of the code, which identifies the manufacturer or distributor, to expand the "Labeler Code" segment to four characters. The National Drug Code, Product Code, and Package Code configurations used to describe these drugs, or any drugs added to the product line, remain the same, i.e., a four-character Product Code and a two-character Package Code. A manufacturer or distributor may either retain alphanumeric characters that are already used in the Product Code and Package Code segments of the National Drug Code or convert these alphanumeric characters to all numeric digits. The manufacturer or distributor shall inform FDA of a decision to convert the alphanumeric characters to all numeric digits.

(2) If a registered establishment or distributor has not previously participated in the National Drug Code System or in the National Health Related Items Code System, FDA uses the National Drug Code numbering system in assigning a number, as follows (only numerals are used):

(i) The first 5 numeric characters of the 10-character code identify the manufacturer or distributor and are known as the Labeler Code. FDA will expand the Labeler Code from five to six numeric characters when the available five-character code combinations are exhausted. FDA will assign Labeler Code numbers and provide them to the registrant along with the validated copy of Form FDA-2656. Any registered firm that does not have an assigned Labeler Code will be assigned one when registration and listing information are submitted.

(ii) The last 5 numeric characters of the 10-character code identify the drug and the trade package size and type. The segment that identifies the drug formulation is known as the Product Code and the segment that identifies the trade package size and type is known as the Package Code. The manufacturer or distributor will assign the Product Code and the Package Code before drug listing and include these codes in Form FDA-2657 (Drug Product Listing). The manufacturer or distributor may use either of two methods in assigning the Product and Package Codes: a 3-2 Product-Package Code configuration (e.g., 542-12) or a 4-1 Product-Package Code configuration (e.g., 5421-2). A manufacturer or distributor with a given Labeler Code shall use only one such Product-Package Code configuration and shall use this same configuration in assigning the Product-Package Codes for all drugs included in the drug listing. The manufacturer or distributor shall report to FDA the Product-Package Code configuration used in assigning these codes.

(iii) If the drug formulation is a Type A medicated article intended for use in the manufacture of an animal feed, FDA assigns a separate Product Code only for each variation of level of active drug ingredient.

(3) FDA requests but does not require that the NDC number appear on all